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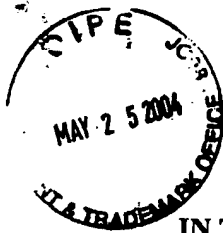
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Patent  
Attorney's Docket No. 033053-025

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

MAY 23 PM 1:14

In re Patent Application of )  
Kenneth C. CUNDY, et al. )  
Application No.: 09/972,425 ) Group Art Unit: 1616  
Filed: October 5, 2001 ) Examiner: Barbara Badio  
For: BILE-ACID DERIVED COMPOUNDS ) Confirmation No.: 5701  
FOR PROVIDING SUSTAINED )  
SYSTEMIC CONCENTRATIONS OF )  
DRUGS AFTER ORAL )  
ADMINISTRATION )

**TRANSMITAL LETTER**

Assistant Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450  
**PETITIONS BRANCH**

Sir:

Enclosed is a Request for Refund in the above-referenced application.

Applicants submit herewith copies of the Petition Decision, the Notice of Appeal and the Three Month Petition for Extension of Time.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in triplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: Melissa M. Hayworth  
Melissa M. Hayworth  
Registration No. 45,774

P.O. Box 1404  
Alexandria, Virginia 22313-1404  
(703) 836-6620

Date: May 25, 2004



STATUS AND ENTRY  
BRANCH

Patent  
Attorney's Docket No. 033053-025 23 PM 1:14

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of	)	
	)	
Cundy, Kenneth C. et al.	)	Group Art Unit: 1616
	)	
Application No.: 09/972,425	)	Examiner: Badio, Barbara P.
	)	
Filed: October 5, 2001	)	Confirmation No.: 5701
	)	
For: Bile-Acid Derived Compounds for	)	
Providing Sustained Systemic Concentrations	)	
of Drugs after Oral Administration	)	
	)	
	)	

**REQUEST FOR REFUND**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants hereby request a refund of the Notice of Appeal fee and Petition for Three Month Extension of Time fee in the above-referenced application.

This request is being made based on the following facts.

A first election of species requirement was issued on January 15, 2003. This requirement was traversed in a response filed on March 17, 2003. The election of species requirement and the generic group as defined by the Examiner was repeated and made final in the Office Action mailed on September 29, 2003. Applicants petitioned the Commissioner under the provisions of 37 C.F.R. §§1.144 and 1.181 to review and withdraw the restriction requirement maintained in the above-identified patent application on December 29, 2003. The Petition was not decided until April 19, 2004. Therefore, to maintain pendency of the above-identified application, Applicants were forced to file a Petition for Three Month extension of time and a Notice of Appeal.

As set forth in the Petition Decision, our petition for withdrawal of the Restriction Requirement has been granted. As a consequence to this decision, the last Office Action has been withdrawn and the application has been forwarded to the Examiner for further consideration.

Copies of the Petition Decision, Notice of Appeal and Three Month Petition for Extension of Time are attached.

Accordingly, Applicants respectfully request a refund of the Notice of Appeal fee (\$330.00) and Petition for Three Month Extension fee (\$950.00) for a total of \$1280.00 to be made to Deposit Account No. 02-4800.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: May 25, 2004

By: 

Melissa M. Hayworth

Registration No. 45,774

P.O. Box 1404  
Alexandria, Virginia 22313-1404  
(703) 836-6620



UNITED STATES PATENT AND TRADEMARK OFFICE

APR 19 2004

MAY 25 2004

BURNS, DOANE, SWECKER & MATHIS LLP  
P. O. BOX 1404  
ALEXANDRIA, VA 22313-1404

In re Application of  
Kenneth C. Cundy et al  
Serial No.: 09/972,425  
Filed: October 5, 2001  
Attorney Docket No.: 033053-025

COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
P.O. Box 1450  
ALEXANDRIA, VA 22313-1450  
www.uspto.gov

BURNS, DOANE, SWECKER & MATHIS, L.L.P.  
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APR 20 2004

DOCKETED

PETITION DECISION

APR 21 04

This is in response to the petition under 37 CFR 1.144, filed December 29, 2003, requesting withdrawal of an improper restriction requirement.

#### BACKGROUND

A review of the file history shows that this application was filed under 35 U.S.C. 111 on October 5, 2001, and contained claims 1-20. In a first Office action, mailed January 15, 2003, the examiner required an election of species to be made by applicants, and set forth some representative examples of species without limiting applicants to choosing therefrom.

Applicants replied on March 17, 2003, electing the species identified by compound 230 and identified claims 1-10 and 19-20 as reading thereon.

The examiner mailed a new Office action to applicants on May 2, 2003, acknowledging applicants election of compound 230 and then defined a subgenus of the generic compound of formula 1 by defining variables X, R<sup>1</sup>, R<sup>2</sup>, Z, M, Q<sup>b</sup> and D'. Claims 5-10 and 19 were then examined and claims 1-4, 11-18 and 20 withdrawn from consideration as being drawn to a non-elected invention. Claims 5 and 19 were then rejected under 35 U.S.C. 112, second paragraph, as indefinite. Claims 6-10 were objected to as containing non-elected inventions.

Applicants replied on August 4, 2003, amending claims 1, 4-10 and 19. Claims 2 and 11-17 were canceled. Replies to the rejection were made and the election of species requirement again traversed with respect to the subgeneric concept developed by the examiner.

The examiner mailed a Final Office action to applicants on September 29, 2003, responding to the traversal by stating that the claims were directed to several patentably distinct inventions and made the requirement Final. Claims 5-10 were again objected to as containing non-elected inventions and their cancellation required. The Office action was made Final.

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Applicants replied on December 29, 2003, by filing this petition requesting that the requirement be withdrawn. Applicants argue that only an election of species within the genus has been required by the examiner and that the examiner has then defined applicants' inventive concept based on the elected species and has restricted examination thereto improperly based on the guidelines of M.P.E.P. 803.02. Further the examiner has not made a restriction between the compound and method claims, but has acted as if there had been and thus not examined the method claims.

## DISCUSSION

Restriction practice under 35 U.S.C. 121 can be divided into two distinct parts. In the first an examiner may define independent and distinct inventions (e.g. - a composition and a method of using) claimed by an applicant and require applicant to choose between them for prosecution purposes. In the second an examiner in order to determine a proper starting point for examination of related, but distinct, inventions (those encompassed by a generic description) may require an election of species. In some instances, the two procedures may be cumulative wherein a election between distinct inventions (e.g. - a compound and a method of using the compound) is made and then an election of species required within the elected group because of the plethora of species claimed within a genus. Specific guidelines are set forth for each type of requirement as well as guidelines for an examiner's action following election from either type of requirement.

In this instance, although the examiner alleges in the last Office action that there are a number of patentably distinct inventions claimed, no formal restriction requirement has been made between them. The examiner has required only an election of species within the compounds set forth in the claims. As such the examiner is required to follow the guidelines set forth in M.P.E.P. 803.02. To some extent the examiner has done that by examining the elected species and determining that it is free of the prior art and has then expanded the search and examination of the species to a number of related species, also finding them free of the prior art. Where the examiner has erred is in then deciding that all applicants are entitled to is the species or subgeneric concept developed from the species by the examiner which has actually been examined. This is not in accord with *In re Weber* and other cases cited in M.P.E.P. 803.02. M.P.E.P. 803.02 requires the examiner after finding the elected species to be patentable to conduct an examination of a representative number of related species and then, if the examined species are also found to be free of the prior art to allow the entire genus. This the examiner has not done.

The examiner has indicated that method claim 1, if limited to the same scope as the compound claims, would also be considered allowable, but has as yet declined to allow such claims since claim 5 remains objected to. However, no formal restriction between the method and compound claims has been made and both types of claims must therefor be examined.

## DECISION

The petition is **GRANTED**.

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**The application will be forwarded to the examiner for further consideration not inconsistent with this decision.**

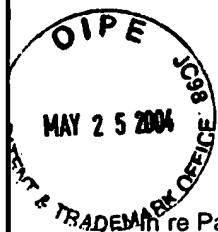
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**As a consequence of this decision the last Office action is withdrawn and the examiner directed to issue a new Office action.**

Should there be any questions about this decision please contact William R. Dixon, Jr., by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0519 or by facsimile sent to the general Office facsimile number, 703-872-9306.



Bruce M. Kisliuk  
Director, Technology Center 1600



Patent  
Attorney Docket No. 033053-025

STATUS AND ENTITY  
BRANCH

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

2004 MAY 28 PM 1:14

In re Patent Application of  
Cundy, Kenneth C. et. al.

Application No.: 09/972,425

Filing Date: October 5, 2001

Title: Bile-Acid Derived compounds for Providing Sustained Systemic Concentrations of Drugs after Oral Administration

Group Art Unit: 1616

Examiner: BADIO, BARBARA P

Confirmation No.: 5701

NOTICE OF APPEAL

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

All finally rejected claims in the decision of the Primary Examiner dated September 29, 2003 are hereby appealed to the Board of Patent Appeals and Interferences.

- ☐ The appeal fee was previously paid on \_\_\_\_\_. Therefore, no Appeal fee is now required.
- ☒ Enclosed is the Appeal fee of: ☐ \$165.00 (2401) ☒ \$330.00 (1401)
- ☐ Please charge the Appeal fee of ☐ \$165.00 (2401) ☐ \$330.00 (1401) to Deposit Account No. 02-4800.
- ☒ A Petition for Extension of Time is enclosed.
- ☐ Small entity status is hereby claimed.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

P.O. Box 1404  
Alexandria, Virginia 22313-1404  
(703) 836-6620  
Date: March 29, 2004

By

Melissa M. Hayworth

Registration No. 45,774

DOCKETED  
filed 3/29/04



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE STATUS AND ENTITY  
BRANCH

In re Patent Application of

Cundy, Kenneth C. et. al.

Application No.: 09/972,425

Filing Date: October 5, 2001

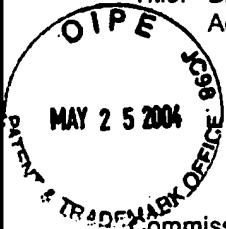
Title: Bile-Acid Derived compounds for Providing Sustained Systemic Concentrations of Drugs after Oral Administration

Group Art Unit: 1616

Examiner: BADIO, BARBARA P

Confirmation No.: 5701

MAY 28 PM 1:14



PETITION FOR EXTENSION OF TIME

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The following extension of time is requested to: Respond to an Office Action dated September 9, 2003

three months to March 29, 2004 ☐ \$475.00 (2253) ☒ \$950.00 (1253)

- ☐ The shortened statutory period has been reset by an Advisory Action dated \_\_\_\_\_.
- ☒ An extension fee in the amount of \$ 950.00 is enclosed.
- ☐ Charge \$ \_\_\_\_\_ to Deposit Account No. 02-4800.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

P.O. Box 1404  
Alexandria, Virginia 22313-1404  
(703) 836-6620

Date: March 29, 2004

By Melissa M. Hayworth  
Melissa M. Hayworth  
Registration No. 45,774

DOCKETED  
filed 3/29/04  
EJ